REMARKS/ARGUMENTS

The rejections presented in the Office Action dated April 29, 2009 (hereinafter Office Action) have been considered. Claims 61-73, 75-93 and 98-104 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

The Office Action rejected claims 61-93 and 98-104 under 35 U.S.C. §102(b) or §103(a) as being anticipated by or obvious over U.S. Patent Application Publication US 2004/0002742 (Florio). Applicants respectfully submit that this rejection cannot be sustained, particularly in view of the amendments to independent claims 61 and 98 above.

The Office Action cites paragraphs 0065, 0066, and 0070, where Florio discusses determining which one of multiple pacing therapies is most effective at reducing or minimizing sleep disturbance. The Office goes on to say that it would have been obvious to assess how effective the therapy is and then reduce the negative impact of the therapy in order to properly treat apnea.

Florio acknowledges that its sleep disturbance metrics (frequency and/or number of sleep disturbance events) "act as a surrogate for sleep apnea", and states that therapies that reduce sleep disturbance events "are expected to additionally treat sleep apnea". See paragraph 0070 of Florio. Since sleep disturbance is considered a surrogate for sleep apnea, the person of ordinary skill who reads Florio would reasonably interpret Florio's technique for determining which pacing therapies reduce or minimize sleep disturbance as a technique to assess the efficacy of the therapies.

Independent claim 61 distinguishes over these teachings of Florio by reciting not only "circuitry configured to assess an efficacy of the therapy", but also reciting "circuitry configured to assess a negative impact of the therapy on a patient". To make clear that these claim features are distinct, claim 61 is being amended to specify that the circuitry to assess efficacy assesses the efficacy "based on one or more first conditions of the detected patient conditions", and to specify that the circuitry to assess negative impact assesses the negative impact "based on one or more second conditions of the detected patient

conditions". Claim 61 also now specifies that the first condition(s) differ from the second condition(s) at least in part. See e.g. pp. 18-19 of the specification for support. Applicants respectfully submit that these clarifying amendments now fully distinguish claim 61 over Florio. The rejection of claim 61, and of its dependent claims 62-93, should be withdrawn.

Independent claim 98 also distinguishes over the teachings of Florio because it recites circuitry configured to assess a negative impact of the therapy on a patient. To make clear that such circuitry differs from circuitry that may be used to carry out Florio's technique for determining which therapies reduce or minimize sleep disturbance, claim 98 is being amended to specify that the circuitry to assess negative impact assesses the negative impact "based on at least one first condition of the detected patient conditions *other than* sleep fragmentation" (emphasis added), where "sleep fragmentation" encompasses the sleep disturbance metrics discussed in Florio. Support for the amendment can be found e.g. at pp. 18-19 of the specification. Applicants respectfully submit that this amendment now fully distinguishes claim 98 over Florio. The rejection of claim 98, and of its dependent claims 99-104, should be withdrawn.

The rejections of a number of the dependent claims also deserve some discussion. Dependent claims 70-92 were summarily rejected (see page 4 of the Office Action) on the grounds that Florio's therapy control system (220) "is inherently configured to adapt the [sic: as] specified since the device allows reprogramming of the control system and thus is configured to be adaptable to whatever needs." (The Office Action also stated that no particular stimulation regimen is specified for the therapy or the needs of the particular patient, thus one therapy may work for one patient and not another.) Applicants respectfully traverse. To establish inherency, extrinsic evidence must make clear that the missing descriptive matter (e.g. that Florio's system is configured to adapt the therapy as set forth in the claims) is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. See e.g. MPEP § 2112(IV). Probabilities or possibilities, e.g., the possibility that Florio's system *may be* reprogrammed to adapt the therapy in accordance with any of the rejected claims, are not sufficient to assert inherency. The Office Action fails to provide any convincing rationale or evidence to show how the

features of *any* of claims 70-92 are necessarily present in Florio. In the absence of such evidence, no *prima facie* rejection has been made. The rejections of each of claims 70-92 should be withdrawn for this additional reason.

To the extent Applicants have not responded to any characterization by the Examiner of the asserted art or of Applicants' claimed subject matter, or to any application by the Examiner of the asserted art to any claimed subject matter, Applicants wish to make clear for the record that any such lack of response should not be interpreted as an acquiescence to such characterizations or applications. A detailed discussion of each of the Examiner's characterizations, or any other assertions or statements beyond that provided above is unnecessary. Applicants reserve the right to address in detail any such assertions or statements in future prosecution.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.059PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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